Remarks

Objections to the Claims:

Claim 13 has been objected to because of informalities. Applicants have amended the claim as recommended by the Examiner to obviate the objection.

Double Patenting:

Claims 13, 16-17, and 22-24 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-13 and 18-21 U.S. Patent 7,098,032 ('032). It is the Applicants' opinion that rejection of the claims on the ground of nonstatutory obviousness-type double patenting over U.S. Patent 7,098,032 is inappropriate. Claims 11 and 18 of '032:

11. A particle for delivering a nucleic acid to a cell formed by the process comprising:
    a) condensing a nucleic acid with a polycation to form a complex;
    b) adding a polyanion to the complex to form a tertiary complex; and,
    c) crosslinking the polyanion to the polycation to form a particle.
22. A process for delivering a nucleic acid to a cell comprising:
    a) condensing a nucleic acid with a polycation to form a complex,
    b) adding a polyanion to the complex to form a tertiary complex,
    c) crosslinking the polyanion to the polycation to form a particle; and,
    d) contacting the cell with the particle.

encompass a method for using a genus of polycation, in combination with a sequentially added polyanion, in forming a nucleic acid particle. The skilled artisan would recognize that any polycation capable of condensing nucleic acid would be useful in practicing the invention of '032. '032, which is the later filed, discloses over 14 classes of polycations and over 70 specific polycations. '032 does not *claim* any specific polycation, nor are the *claims* directed to any specific polycation or class of polycations.

'032 teaches and claims the used of polycation only in the context of also adding a polyanion after condensation of the nucleic acid with the polycation. "The fundamental reason for the rule is to prevent unjustified timewise extension of the right to exclude granted by a patent." The composition of instant claim 1, limited to an amphiphilic membrane active polyvinylether, would not extend the method claimed in '032.

> In re Kaplan, 789 F.2d 1574, 229 USPQ 678 (Fed. Cir. 1986). Kaplan had been issued a patent on a process of making chemicals in the presence of an organic solvent. Among the organic solvents disclosed and claimed as being useful were tetraglyme and sulfolane. One unclaimed example in the patent was specifically directed to a mixture of these two solvents. The claims in the application of Kaplan and Walker, the application before the Office, were directed to essentially the same chemical process, but requiring the use of the solvent mixture of tetraglyme and sulfolane. In reversing the double patenting rejection, the court stated that the mere fact that the broad process claim of the patent requiring an organic solvent reads on or "dominates" the narrower claim directed to basically the same process using a specific solvent mixture does not, per se, justify a double patenting rejection.

It is the Applicants' opinion that the Examiner is using an unclaimed disclosure of one type of polycation in '032 that could be cross-linked to a polyanion, to improperly reject the instant claim: "… a double patenting rejection must rely on a comparison with the *claims* in an issued or to be issued patent." Applicants request reconsideration of the double patenting rejection.

Rejection of the claims under 35 USC §102:

Claims 13-17, 19-20, 22, and 25-30 have been rejected under 35 U.S.C. 102(e) as being anticipated by Meier et al (U.S. Patent 6,616,946 ('946)). The Action maintains that the polymers of '946 inherently possess membrane activity. In support of this argument, the Action states that attachment to of an antibody to a cell membrane constitutes membrane activity. The Action has provided no evidence that antibodies as taught by '946 are capable of: altering membrane structure as shown by the antibody inducing one or more of the following effects upon a membrane: an alteration that allows small molecule permeability, pore formation in the membrane, a fusion and/or fission of membranes, an alteration that allows large molecule permeability, or a dissolving of the membrane (from Applicants' definition of membrane activity, page 9 lines 12-23). The Action further states that the delivery vehicle taught by '946 fuses with cells because they are replacements for liposomes. However, liposomes have several properties including: encapsulation of drugs, formation of nucleic acid particles, and, in appropriate compositions, fusion with membranes. '946 teaches "Liposomes have the advantages that they are self-assembling and can encapsulate drugs under physiological conditions." (column 1 lines 36-47) and "Liposomes can be used as templates for formation of the hollow

particles." (column 18 lines 5-26). '946 teaches throughout that their particles are useful for *encapsulation* of agents. '946 does not teach or suggest anywhere that their particles possess the membrane fusion ability of some, but not all, liposomes. The Action states that the Applicants' specification teaches only properties that a membrane active compound may potentially have and not absolute requirements. Applicants respectfully disagree. Dictionary.com defines the words "can" and "may" as follows:

Can:
1. to be able to; have the ability, power, or skill to
2. to know how to
3. to have the power or means to
4. to have the right or qualifications to

May:
1. used to express possibility
2. used to express opportunity or permission

The term "can" is commonly used to expresses *ability*, while the term "may" is commonly used to express permission or *possibility*. These definitions are consistent with those proved by: Merriam Webster, thefreedictionary.com, MSN Encarta, and the Cambridge Dictionary and are consistent with Applicant's usage in their definition of membrane activity.

Applicants have amended claim 13 to further differentiate their polymers from those of '946. Specifically, Applicants have amended claim 13 to recite that the polyvinylether polymers are random copolymers. Support for the amendment can be found in the specification in FIG. 1, FIG. 2, and Example 3 starting on page 13. '946 teaches only block copolymers (abstract, column 8 line 30 to column 9 line 27, column 11 lines 65 to column 12 line 34). Applicants request reconsideration of the rejection.

Rejection of the claims under 35 USC §103:

Claims 23-24 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Meier et al (U.S. Patent 6,616,946) in view of Merdan et al. (Adv Drug Deliv Rev 2002). It is the Applicants' opinion that the amendment and arguments made in response to the 102(e) rejection over Meier et al. are sufficient to obviate the 103 rejection. Applicants request reconsideration of this §103 rejection.

New Claims:

Applicants have added new claims 31-40.

Support for claims 31, 33, 34, 36, and 37 can be found in the specification in FIG. 1, FIG. 2, page 3 lines 19-30, page 5 line 20 to page 6 line 10, example 2 and example 3.

Support for claim 32, 35 and 40 can be found in the specification on page 4 lines 5-7, page 7 lines 30-34 and page 9 lines 12-23, and example 4.

Support for claim 38 and 39 can be found in the specification in FIG. 3, on page 3 line 32-34, page 4 lines 9-14, and page 7 lines 13-28.

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 13-17, 19-20, and 22-40 should be allowable.

Respectfully submitted,

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I hereby certify that this correspondence is being transmitted to the USPTO on this date: 03/07/2008 .

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